In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1804V UNPUBLISHED

CONNIE SUZANN MUNDINGER,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 17, 2021

Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Robert David Proffitt, Proffitt & Cox, LLP, Columbia, SC, for petitioner.

Althea Walker Davis, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

On November 25, 2019, Connie Suzann Mundinger filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on October 6, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the vaccine alleged as causal was administered in Petitioner's left deltoid, and that onset of Petitioner's SIRVA occurred within 48 hours of vaccination.

I. Relevant Procedural History

A few months after the Petition was filed, an initial status conference was held on February 7, 2020. Respondent noted at this time that Petitioner had filed an electronic vaccine administration record from CVS Pharmacy indicating that the October 6, 2018 vaccine had been administered in the *right* deltoid, whereas Petitioner was alleging a *left* arm SIRVA. ECF No. 15. Respondent also observed that CVS Pharmacy normally possessed an additional signed consent form specifying the site of administration, so the issue of situs could be substantiated with additional evidence. *Id.* Petitioner agreed to follow up with the pharmacy and file any outstanding records, including any additional handwritten records documenting the vaccination situs. *Id.*

On March 3, 2020, Petitioner filed a second electronic record from CVS Pharmacy, again indicating that the vaccine was administered in the right deltoid. Ex. 14. Petitioner also stated that she had returned to the CVS Pharmacy that administered the vaccine, but was told that no handwritten vaccination records were available. See Ex. 13 at ¶ 4. Petitioner subsequently moved for subpoena authority to obtain any additional vaccination records (ECF No. 21), which I granted on April 24, 2020. ECF No. 22.

On July 9, 2020, Petitioner confirmed that she was unable to obtain any other outstanding vaccination records. See ECF No. 23 at 1-4. However, after communicating with CVS Pharmacy, Petitioner requested and obtained an amended vaccination record indicating that the vaccine was administered in her left deltoid, as alleged. See Exs. 29-31.

On November 23, 2020, Respondent filed a status report providing counsel's reaction to this claim and addressing the updated evidence. ECF No. 35. The report restated the issues regarding Petitioner's vaccination record, and noted that "a ruling by the court as to the arm of vaccination may be required to advance this claim." *Id.* at 2. Respondent also asserted that Petitioner had not established a SIRVA claim under the Vaccine Injury Table, because the onset of her shoulder pain did not occur within 48 hours of vaccination. *Id.* at 2-3. Petitioner filed a response to Respondent's status report on November 29, 2020. ECF No. 36.

I thereafter issued a Scheduling Order on January 14, 2021, indicating that I was prepared to make findings regarding the site of vaccine administration and the onset of

Petitioner's alleged injury. ECF No. 37. The parties were permitted to file any additional briefing and relevant evidence pertaining to these issues, and I noted that I would thereafter issue a fact ruling. *Id.* The parties filed status reports on March 1, 2021, maintaining their previous positions. ECF Nos. 38-39. Accordingly, the disputed factual issues are now ripe for resolution.

II. Issue

At issue is whether (a) Petitioner received the vaccination alleged as causal in her injured left arm, and (b) Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later

testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

A. Site of Vaccination

Based upon a review of the entire record, I find that Petitioner's October 6, 2018 flu vaccine was likely administered in her left arm, as she contends. I base my finding on the following evidence:

- At an orthopedic appointment on January 23, 2019 (more than three months post-vaccination), Petitioner reported left shoulder pain that started in October 2018. Ex. 3 at 5. Petitioner's orthopedist provided the following assessment: "Subacromial bursitis after flu vaccination of the left shoulder, injected." *Id.* at 6.
- On January 28, 2019, Petitioner underwent an initial physical therapy evaluation. Ex. 4 at 10. Petitioner indicated that she had experienced left shoulder pain and decreased range of motion since a "flu injection into her capsular space" in October. *Id.* The "Mechanism of Injury" was recorded as "flu shot with subsequent adhesive capsulitis." *Id.*

The above-referenced evidence is consistent with Petitioner's situs allegation. As indicated, and in the context of seeking care, Petitioner reported that the vaccine had been administered in her left arm, and that the injury was associated with the vaccination. There is thus reasonable record support for Petitioner's contention about the situs of administration beyond her own allegations. Petitioner has also provided a logical explanation for why the vaccine would likely have been administered in her left arm. Indeed, Petitioner stated in her affidavit that she has lymphedema in her *right* arm, and therefore cannot have any shots administered or her blood pressure taken in that arm. See Ex. 6 at ¶ 5; see also Ex. 2 at 23 (referencing lymphedema in right arm as a result of mastectomy). Petitioner additionally submitted an affidavit from her orthopedist, Kevin K. Nahigian, M.D., who noted that Petitioner reported that the vaccine was received in her left arm. Ex. 8 at ¶ 10.

I acknowledge that the original vaccine administration record filed in conjunction with the Petition (as well as Exhibit 14, which was filed shortly after the initial status conference) memorializes administration of the flu vaccine in Petitioner's right deltoid. Exs. 1 at 4; 14 at 15. However, all other medical records³ and Petitioner's affidavits indicate the vaccine was actually administered in Petitioner's left arm, and I am empowered to weigh contemporaneous records against other evidence in evaluating whether those records, which often are presumed accurate, are in fact so. *Cucuras*, 993 F.2d at 1528; *Camery*, 42 Fed. Cl. at 391. Here, after reviewing the entire record, I am more persuaded by the later medical and testimonial evidence, which not only is consistent with Petitioner's contentions but provides a reasonable explanation for why Petitioner would not have wanted *any* vaccine administered in her right arm. Accordingly,

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³ I do not give great weight to the situs record that CVS created at Petitioner's urging, since it came to be after this case's filing, and is facially inconsistent with actual contemporaneous records. I have, however, found that other evidence sufficiently rebuts the contemporaneous administration evidence.

I find it more likely than not that the vaccine alleged as causal in this case was administered in Petitioner's left arm on October 6, 2018.

B. Onset

Based upon a review of the entire record, I find that the onset of Petitioner's shoulder pain likely occurred within 48 hours of vaccination. Specifically, I base my finding on the following evidence:

- Petitioner was administered a flu vaccine in her left deltoid on October 6, 2018. See discussion supra Part IV.A.
- On December 18, 2018, Petitioner presented to Lexington Medical Center with complaints of progressively worsening left arm pain for two months. Ex. 2 at 4. Petitioner indicated that she experienced intermittent shooting pain from the shoulder down her arm, and she presented with painful range of motion. *Id.* at 4, 6.
- On January 23, 2019, Petitioner underwent an initial orthopedic appointment at Lexington Medical Center for treatment of left shoulder pain. Ex. 3 at 5. The onset of Petitioner's pain was recorded as "10/2018." *Id.* Petitioner's orthopedist provided the following assessment: "Subacromial bursitis after flu vaccination of the left shoulder, injected." *Id.* at 6.
- On January 28, 2019, Petitioner underwent an initial physical therapy evaluation. Ex. 4 at 10. Petitioner was noted as having limited left shoulder range of motion and pain since her flu vaccination in October, and the Date of Onset/Injury was recorded as "[October] 2018." Id.
- Petitioner filed an affidavit (Ex. 6) in conjunction with the Petition, in which she averred that her "left shoulder and arm were extremely painful and sore on the day of the [vaccination] and for days and weeks afterward." *\frac{1}{d}. at \mathbb{9}. Petitioner stated that her symptoms continued despite medication, an epidural steroid injection, and physical therapy. *Id. at \mathbb{9}. 13, 15-23.

As previously described, Respondent has questioned the sufficiency of the evidence filed by Petitioner in support of her claim that her shoulder pain manifested within 48 hours after vaccination. Respondent specifically notes that Petitioner first sought

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⁴ Petitioner additionally filed an affidavit from Michael Scott Mundinger, her husband. Ex. 7. Mr. Mundinger averred that Petitioner experienced immediate pain following her vaccination, and that her symptoms persisted despite medical treatment. *Id.* at ¶¶ 5, 8, 14-20.

medical treatment for left arm pain on December 18, 2018 – 73 days following vaccination – but reported that she had experienced these symptoms for only two months. ECF No. 35 at 2-3. Respondent asserts that this discrepancy in timing (i.e., 73 days vs. two months) undercuts Petitioner's claim that she experienced onset of shoulder pain within 48 hours of vaccination. *Id*.

I have evaluated Respondent's arguments but find them unpersuasive. Although it is true Petitioner's initial post-vaccination records document her shoulder pain as beginning two months earlier, I do not find this evidence precludes an onset within 48 hours of vaccination. Instead, having considered the entire record, I find it most likely that Petitioner was providing a non-literal approximation of her symptom onset at her initial post-vaccination medical appointment. My conclusion is supported by Petitioner's subsequent records, which contain entries clearly tying the onset of her pain to the October 2018 vaccination, and indicating her symptoms began at that time. See, e.g., Exs. 3 at 5-6; 4 at 10. These records are also consistent with Petitioner's affidavit, which describes immediate post-vaccination shoulder pain that worsened over time. Ex. 6 at ¶ 9. Considered as a whole, the above records preponderate in favor of an onset within 48 hours of vaccination.

Finally, although Ms. Mundinger did not seek treatment for her left shoulder injury until approximately two months after vaccination, I do not find this delay to be dispositive regarding the issue of onset. Indeed, Petitioner's medical records and affidavits reflect a pattern similar to other SIRVA claims, in which injured parties delay treatment, often based on the fair assumption that their pain will be transitory. See, e.g., Tenneson v. Sec'y of Health & Human Servs., No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), review denied, 142 Fed. Cl. 329 (2019), (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); Williams v. Sec'y of Health & Human Servs., 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because petitioner underestimated the severity of her shoulder injury); Knauss v. Sec'y of Health & Human Servs., 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting a three-month delay in seeking treatment).

Accordingly, I find there is preponderant evidence to establish that the onset of Ms. Mundinger's left shoulder pain occurred within 48 hours of her October 6, 2018 flu vaccination.

V. Scheduling Order

Respondent shall file a status report, by no later than <u>Monday</u>, <u>August 02</u>, <u>2021</u>, indicating whether he is interested in exploring an informal resolution of Petitioner's claim.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master